

Remarks

Claims 11, 15, 21-24, 26-30, and 32-35 are pending and examined in this application. Claim 31 is amended to more particularly point out and distinctly claim the invention. The claims stand rejected from the Final Office Action of August 9, 2004 and the Advisory Action of December 3, 2004. Applicants respectfully request reconsideration and withdrawal of the current rejections based on the amendments and the following remarks.

Rejections under 35 U.S.C. 112, first paragraph

Claims 11, 15 and 20-30 stand rejected under 35 U.S.C. 112, first paragraph for failing to comply with the enablement requirement. Withdrawal of these rejections are respectfully requested for the following reasons.

Applicants again assert that the instant claims are fully enabled. Claims 11 and 21-24 are directed to methods of monitoring the progression of HIV infection or AIDS in a patient. The methods comprise measuring the number of pDC2 cells in a lymphoid tissue or blood sample from the patient, and comparing the measured number with a control sample from subjects free of HIV infection or AIDS, where a number pDC2 cells in the patient sample below the number in the control indicates that the HIV infection or AIDS is progressing. Claims 15 and 26-28 are directed to methods of assessing the effectiveness of a composition in treating HIV infection or AIDS. The methods comprise measuring the number of pDC2 cells in a lymphoid tissue or blood sample from the patient, and comparing the measured number with a sample from the patient before undergoing treatment, where an increase in the number of pDC2 cells from the sample taken after treatment indicates that the composition is effective. Claims 30 and 32-35 are directed to methods of monitoring the progression of HIV infection or AIDS in a patient. The methods comprise measuring the number of pDC2 cells in a lymphoid tissue or blood sample from the patient, and comparing the measured number with a control sample from subjects where the HIV infection or AIDS is progressing, where a

number of pDC2 cells in the patent sample above the number in the control indicates that the HIV infection or AIDS is progressing.

Each aspect of these claims are fully enabled. Measuring the number of pDC2 cells in a lymphoid tissue or blood sample can be easily done given the instant specification, by simply counting the number of CD4+, CD3- and CD11c- cells present, as discussed on page 29, line 7 of the specification. Additionally, the specification establishes a correlation between the number of pDC2 cells and the progression of AIDS or HIV infection, since the Example at pages 28-top of page 32 establishes that pDC2 cells are the natural interferon-producing cells (see in particular Table 1), and the Example at pages 32-39 establish that interferon production negatively correlates with HIV progression and positively correlates with the effectiveness of HIV treatment (as determined by CD4<sup>+</sup> cell counts). Given this data, the skilled artisan would conclude that the quantity of pDC2 cells negatively correlates with HIV progression and positively correlates with the effectiveness of HIV treatment. This correlation was confirmed in Siegal et al., 2001, AIDS 15:1603-1612, and Feldman et al., 2001, Clin. Immunol. 101:201-210, as discussed in the Amendment and Reply dated May 17, 2004.

Furthermore, it would take only routine experimentation to establish controls for any individual. Such reference ranges could be established simply by drawing blood from the appropriate population and counting pDC2 cells using, e.g., the cell sorting methods established in the instant specification. Such a determination would not be considered undue experimentation, since there is no uncertainty in the methods used to make those determinations.

In light of the above discussion, Applicants respectfully request withdrawal of the enablement rejections under 35 U.S.C. 112, first paragraph.

Conclusion

Based on the claim amendments and the above discussion, Applicants respectfully request withdrawal of all rejections and passage of the claims to allowance. If there are any minor matters that prevent allowance of the claims, the PTO may contact the undersigned attorney to resolve those matters.

It is believed that the enclosed check for \$1810, to cover the Request for Continued Examination and a three month extension of time, is all that is required with this Reply. If there are any unanticipated fees required to maintain pendency of this application, those fees can be withdrawn from Deposit Account No. 01-1785.

Respectfully submitted

AMSTER, ROTHSTEIN & EBENSTEIN LLP  
Attorneys for Applicant  
90 Park Avenue  
New York, NY 10016  
(212) 336-8000

Dated: New York, New York  
February 9, 2004

By:   
Elie H. Gendloff  
Registration No.: 44,704